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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,883	11/29/2005	Ask Puschl	434-US-PCT	6788
45821	7590	06/30/2009		
LUNDBECK RESEARCH USA, INC.			EXAMINER	
ATTENTION: STEPHEN G. KALINCHAK, LEGAL			CHANG, CELIA C	
215 COLLEGE ROAD			ART UNIT	
PARAMUS, NJ 07652			PAPER NUMBER	
			1625	
			MAIL DATE	
			DELIVERY MODE	
			06/30/2009	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/551,883

**Applicant(s)**

PUSCHL ET AL.

**Examiner**

Celia Chang

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 38-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Amendment and response filed by applicants dated April 3, 2009 have been entered and considered carefully. Terminal disclaimers are acceptable.

Claims 1-37 have been canceled. Claims 38-52 are pending.

2. Claims 39, 40, 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The currently amended scope of claims 39, 40, 43 lacks antecedent basis in the specification. Please note that on pages 12-19 wherein the preferred embodiment was described, nowhere the combination of R5 being halogen, R9 being halogen and at least one other R1-R4, R6-R8 must not be hydrogen was described. The amended scope is therefore NEW MATTER. While species of R5 and R9 are fluoro or chloro, there may be an additional substituent of fluoro, chloro, methyl or methoxy were disclosed, however, species do not add up to a subgeneric description unless antecedent basis was found in the specification. Nowhere in the specification provided support that when R5 and R9 are "halogen" that R1-R4 and R6-R8 are nonhydrogen and are selected from the mix and matching moieties as now amended. As a matter of fact, the first species of claim 38 have all R1-R4, R6-R8 being hydrogen.

This is a new matter rejection. Removal of all new matter is required. In re Russmussen 210 USPQ 325.

After removal of new matter and the claims are restored to the previous version (claim 17, *R1-R9 are optionally hydrogen.....at least one of R1, R2, R4, R5, R6, R7, R8, R9 is different from hydrogen; also provided that when R3 is methyl, then at least one of R1, R2, R4, R5, R6, R7, R8, R9 is different from hydrogen*), the rejections of record are discussed.

3. The rejection of claims 17-26, 28-34, 38 (17-26, 28-34 canceled) under 35 USC 103(a) over US 4,198,419 is dropped in view of applicants argument that the intermediated of Ong et al.

'419 must not have the 4-position of the piperidinyl ring to be hydrogen because of the requirement for making a cyclic product. Therefore, modification of the '419 intermediate to the instant 4-unsubstituted piperidine would not be obvious.

4. The rejection of claims 17-26, 28-34, 37, 39-51 (17-26, 28-34, 37 are canceled) under 35 USC 102(e) over Rubland et al. '407, '884, '238 is maintained for reason of record.

Applicants argued that claims cannot be anticipated by adding two species together. Please note that the decisions by In re Arkley 172 USPQ 524, In re Schaumann 197 USPQ 5, In re Petering 133 USPQ 275, Ex Parte A 17 USPQ2d 1716, the court has clearly set forth guidelines that when small clearly delineated genus such as found in Rubland '407, '884 or '238 with explicit guidance by species, anticipation is found. The specific compound does not have to be explicitly named. Please note that the compounds as exemplified in the references showed variation of moieties, positions and number of substitutions guiding one skilled in the art to conclude that the prior art disclosed a compound with one halogen on each phenyl ring of formula I. It is applicants that need to show that why a 2-fluoro, 6-fluoro compound is unobvious therefore would not be considered within the scope of the exemplified species of the prior art for which anticipatory conditions set forth by In re Arkley 172 USPQ 524, In re Schaumann 197 USPQ 5, In re Petering 133 USPQ 275, Ex Parte A 17 USPQ2d 1716, was the situation.

5. The rejection of claims 17-26, 28-34, 37-52 (17-26, 28-34, 37 are canceled) under 35 USC 103(a) over Rubland '407, '884, '238 is maintained for reason of record.

Applicants argued that the references are subject to obligation of common assignee, thus, are under 103(c) condition. Please note that the assignment of the instant case was recorded in Oct. 2005. Therefore, no record indicated that at the time the invention was made i.e. 2003 priority date, common ownership was recorded.

6. The rejection of 17-26, 28-34, 37, 39-52 (17-26, 28-34, 37 are canceled) under 35 USC 103(a) over US 6,699,864 is maintained for reason of record.

Applicants argued that formula III of '864 is not within the description of the instant invention because in formula III R6-R9 are all hydrogen and the instant claims has at least one of R6-R9 being not hydrogen.

This is erroneous. The proviso of the claims as originally filed requires that:

*"provided that at least one of R1, R2, R4, R5, R6, R7, R8, R9 is different from hydrogen; also provided that when R3 is methyl, then at least one of R1, R2, R4, R5, R6 R7, R8, R9 is different from hydrogen"* (see p.80 claim 1 as originally filed)

Therefore, no antecedent basis was found for attorney's allegation that the non-hydrogen moiety must be on the R6-R9 ring. The scope as originally filed is one of R1, R2, R4, R5, R6, R7, R8, R9 is nonhydrogen.

The rejection is maintained and the requirement of submitting record as recited in MPEP 715.01(b)-(c) is maintained also. Please note that this is **not** a double patenting issue and filing of a terminal disclaimer cannot obviate the requirement in identifying which entity is the "first" to invent.

7. The rejections of claims 17-26, 28-34, 37, 39-52 (17-26, 28-34, 37 are canceled) under the judicially created doctrine of obviousness type double patenting over Rubland et al. '238 or Rubland '407, '884 in view of '864 are dropped in view of the acceptable terminal disclaimer filed by applicants.

8. The requirement of naming the first inventive entity among the instant application and the issued patent based on anticipatory subject matter according to the guidelines of In re Arkley 172 USPQ 524, In re Schaumann 197 USPQ 5, In re Petering 133 USPQ 275, Ex Parte A 17 USPQ2d 1716 is maintained for reason of record. The same explanation as clearly as delineated supra in section 4, only here it is applicable to the claims, is hereby incorporated by reference.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**10.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Jun. 24, 2009*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*